EXHIBIT 9

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ORIGINAL ARTICLE

Mesh removal following transvaginal mesh placement: a case series of 104 operations

Naama Marcus-Braun · Peter von Theobald

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Abstract
Introduction and hypothesis The objective of the study was to reveal the way we treat vaginal mesh complications in a trained referral center.
Methods This is a retrospective review of all patients who underwent surgical removal of transvaginal mesh for mesh-related complications during a 5-year period.
Results Eighty-three patients underwent 104 operations including 61 complete mesh removal, 14 partial excision, 15 section of sub-urethral sling, and five laparoscopies. Main indications were erosion, infection, granuloma, incomplete voiding, and pain. Fifty-eight removals occurred more than 2 years after the primary mesh placement. Mean operation time was 21 min, and there were two intraoperative and ten minor postoperative complications. Stress urinary incontinence (SUI) recurred in 38% and cystocele in 19% of patients.
Conclusions In a trained center, mesh removal was found to be a quick and safe procedure. Mesh-related complications may frequently occur more than 2 years after the primary operation. Recurrence was mostly associated with SUI and less with genital prolapse.

Keywords Mesh complications · Mesh removal · Pelvic organ prolapse · Stress urinary incontinence · Vaginal mesh

Abbreviations

SUI	Stress urinary incontinence
POP	Pelvic organ prolapse
FDA	Food and Drug Administration
TVT	Tension-free vaginal tape
IVS	Intravaginal sling
TOT	Trans-obturator tape
UTI	Urinary tract infection
POP-Q	Pelvic organ prolapse quantification

N. Marcus Braun · P. von Theobald (✉)
Department of Gynecology Obstetrics and Reproductive Medicine,
University Hospital of Caen,
Boulevard Georges Clémenceau,
14033 Caen cedex, France
e mail: vontheobald p@chu caen.fr

Introduction

Vaginal mesh surgeries have become very popular in the last few years. The rising use of adjuvant materials, most often non-absorbable meshes, resulted in dramatic progress and development of new surgical techniques, commercial kits, and publications [1–4]. Two randomized trials using transvaginal mesh placement kits have been published recently, revealing better results and lower recurrence rate when compared to classical methods with autologous tissues [5, 6]. Although the use of vaginal mesh to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI) seems very promising, there are complications associated with the techniques and others with the mesh itself. Most of the transvaginal kits available today to treat incontinence and genital prolapse require trocars to introduce the mesh. The introduction of the mesh can cause intra- and postoperative complications, especially when the anatomical knowledge of the pelvic structures and the correct passage of the trocar is lacking. Complications related to the adjuvant materials and risk factors are well described in the literature [7–9]. Mesh-related complications can be treated locally in certain cases, like small erosions without signs of infection and in case of incomplete voiding (described mainly after sub-urethral slings). However, with other mesh-related complications,

including repeat erosion, infection, malposition, pain, and mesh shrinkage, complete mesh removal is sometimes unavoidable. Since most commercial kits were recently introduced, there are no sufficient data in the literature regarding long-term complications of vaginal mesh surgeries and the appropriate way to treat them. Small case series, between 12 to 19 cases, have been published recently describing the procedure used for vaginal mesh excision, indications, and complications [10–12]. However, obtaining a precise conclusion from these series is difficult because of their small size. The US Food and Drug Administration (FDA) has published an alert in October 2008 [13] with regard to transvaginal placement of surgical mesh. The alert was published after receiving over 1,000 reports of complications that were associated with surgical mesh devices used to repair POP and SUI. The FDA recommendations emphasize the need to obtain specialized training for each mesh placement technique and to be aware of its risks.

In the University Hospital of Caen, we applied a protocol for the treatment of POP with vaginal mesh since 2001. With 250 mesh operations for POP and SUI performed every year, the team is very experienced. Since the University Hospital of Caen is a tertiary referral center, we treat ours as well as the peripheral's mesh complications. In the light of the FDA alert and the recent publications of vaginal mesh removal, we have decided to conduct a case series study and to include all surgical mesh removal performed in our institution in order to reveal complications and outcomes of these procedures in a trained tertiary referral center.

Materials and methods

A retrospective study was conducted in the University Hospital of Caen including all patients who underwent surgical removal of transvaginal mesh for mesh-related complications between January 2004 and December 2008. The current law in France does not require an approval of institution review board for retrospective studies. Operations have been performed by the surgeon team of the gynecological department. Data were collected from medical records including patient's age, primary operation for mesh placement, characteristics of mesh removal operation which included indications, site (vesico-vaginal, recto-vaginal, and sub-urethral), type of mesh excision (partial, complete, section or laparoscopy), intra- and postoperative complications, repeat procedures, operation time, hospital stay, and recurrence of POP or SUI. All patients were evaluated for complications and outcomes during their hospital stay, 6 weeks and 6 months after the operation. Additional follow-up and assessment was done upon need and symptoms.

The aims of the study were to evaluate the intra- and postoperative complications of mesh removal procedures, operation time, hospital stay, and outcomes with regards to anatomical and functional results.

Surgical techniques

Section of sub-urethral mesh can be carried out under local anesthesia in most patients. A small sagittal cut is performed 1 cm under the urethral meatus in order to reach the band, followed by a sharp cut of the band in one of its arms. The vagina is closed with two or three separated absorbable sutures. *Partial removal* of the mesh is performed under general or spinal anesthesia in order to have a good exploration of the mesh. The extruded part of the mesh is removed and the remaining mesh is carefully examined for signs of infection. The vagina is closed with running locked absorbable suture. *Complete removal* of vaginal mesh is performed under general or spinal anesthesia. For complete removal of the anterior mesh, a midline full-thickness incision is performed on the anterior vagina, extending up to 2 or 3 cm from the urethral meatus. The bladder is dissected away from the vaginal wall, and the paravesical fossas are opened until the ischial spine and the arcus tendineous of the levator ani are reached. The body of the mesh is trapped and the surrounding tissues are carefully dissected away. The mesh is then removed from under the bladder and the arms from the paravesical fossas. For complete removal of the posterior mesh, a midline full-thickness incision is performed on the posterior vagina extending up to 1 cm from the uterus cervix or vaginal vault. The pararectal fossas are opened until the ischial spine and the sacrospinous ligaments are reached. The body of the mash is trapped and the surrounding tissues are carefully dissected away. The mesh is then removed with the arms from the pararectal fossas. In cases of infection, an attempt is made to remove all the mesh, including body and arms, along with all the abnormal discharge or pus. The vagina is closed with running locked absorbable suture. *Laparoscopy* to remove tension-free vaginal tape (TVT) is made through extraperitoneal insufflation in order to reach the Retzius space. The dissection is carried out until the Cooper's ligaments and the urethra are reached anteriorly and the arcus tendineus fascia pelvis posteriorly, followed by the dissection of the TVT from the pelvic walls. In cases of urinary obstruction, the remaining mesh is removed through vaginal approach.

All the removed meshes are sent for histological and bacteriological examination.

Results

Between January 2004 and December 2008, 83 patients had surgical removal of transvaginal mesh in our gynecological

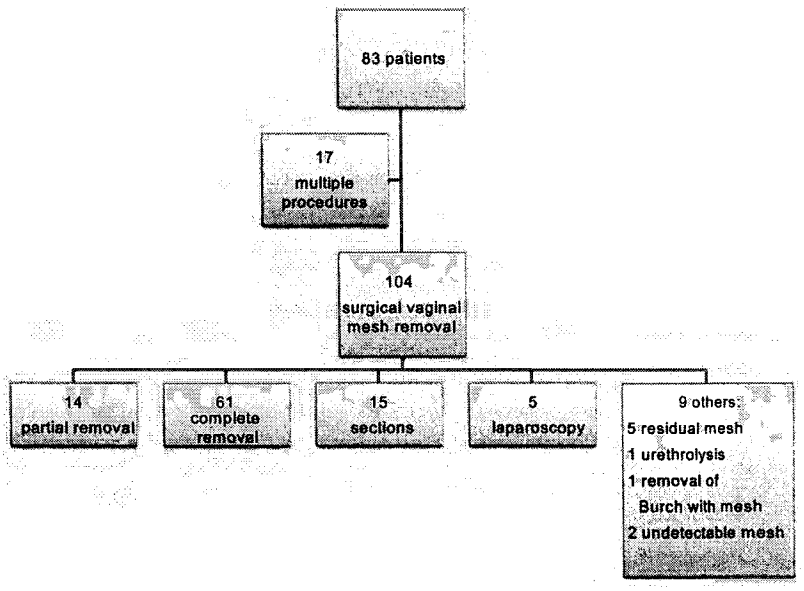

Fig. 1 Flow diagram of the 104 surgical removal of trans vaginal mesh

department. Seventeen patients (20.5%) required more than one operation, and overall, there were 104 operations for mesh removal (Fig. 1). Twenty-eight operations were of recto-vaginal mesh removal, 42 of vesico-vaginal mesh removal, and 37 of sub-urethral sling. Mean age was 62 years (range, 34–84), mean operation time was 21 min (range, 5–65), and mean hospital stay was 3 days (range, 1–10). The different types of the primary transvaginal mesh placement operations are presented in Table 1, while some patients had more than one operation for vaginal mesh placement.

The various indications for the removal of the mesh are presented in Fig. 2 and were in certain cases multifactorial. Erosion, without signs of infection, was the indication for 44 operations; 24 were of vesico-vaginal meshes, 13 of recto-vaginal meshes, seven of sub-urethral slings, and one was intravesical. Infection was described in 30 cases involving abnormal secretion, pus, and fistulization to the skin at the level of the needle scar in some cases. Among the infected cases, five patients had abscess as a presenting symptom, three had fever, and one had infected hematoma 3 weeks after the primary operation. Only seven cases had positive culture, and there was no detection of a specific pathogen (three *Escherichia coli*, two *Staphylococcus aureus*, one Fusobacterium, and one *Streptococcus constellatus*). Nine surgical mesh removals were preformed for pelvic pain, and among them, three patients described dyspareunia and one described pudendal pain. The time interval between the insertion and the removal of the mesh as a function of the various indications is described in Table 2.

Table 3 summarizes the four major groups of surgical vaginal mesh removals. Among 14 patients that underwent section of the band, one patient required recurrent section of the trans-obturator tape (TOT) in the opposite side. Eleven

Table 1 Different types of the primary transvaginal mesh placement operations

Primary mesh operation	Patients (n)[a]
Triple operation for prolapse with prostheses (TOPP)[b]	31
Cystocele mesh	16
IVS posterior ± rectocele mesh	11
TVT/ retropubic IVS	13
TOT/TVT O	21
Laparoscopic Burch operation with mesh	1
Uretex	1
Pelvicol	1
Concomitant vaginal hysterectomy	6

IVS intravaginal sling, *TVT* tension free vaginal tape, *TOT* trans obturator tape, *TVT O* tension free obturator tape

[a] Some patients had multiple mesh operations

[b] TOPP operation included cystocele, rectocele, and level 1 defect repair

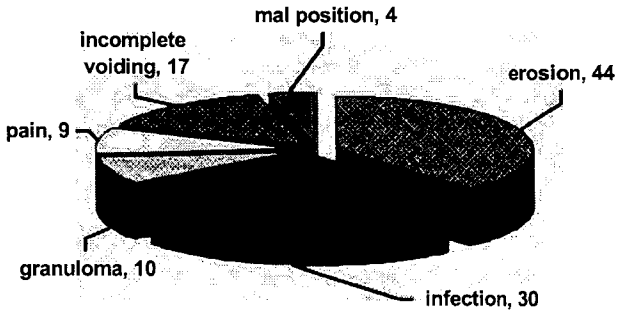

Fig. 2 Various indications for surgical transvaginal mesh removal

Table 2 Distribution of the indications for mesh removal and the delay from the primary operation

Duration	Indication[a]				
	Erosion (44)	Infection (30)	Granuloma (10)	Pain (9)	Incomplete voiding (17)
Within 2 years	26	10	5	2	9
After 2 years	5	5	1	3	2
After 3 years	7	11	3	3	3
After 4 years	4	4	1	1	2
>4 years	2				1
Overall after 2 years (%)	18 (41)	20 (66.6)	5 (50)	7 (77.8)	8 (47)

[a] Some patients had multiple indications

sections were of sub-urethral slings and four sections of the anterior arm of the cystocele mesh. Twelve out of 15 sections (80%) were performed under local anesthesia.

Seventeen patients (20.5%) underwent repeat procedures, and there were 40 operations in this group. The indications for the primary and the sequential interventions are presented in Table 4. Twelve patients were reoperated twice, three went through three interventions, and two patients required four operations until a complete remission of the symptoms was achieved. Twenty-six of the repeated operations were at the same site for the same mesh, ten patients had repeated operation in different sites, and two patients were operated twice for excision of different primary meshes.

Intraoperative complications occurred in two operations: the first was during an attempt to remove TVT by laparoscopy; it was converted into laparotomy due to difficult hemostasis. The other intraoperative complication was during section of retropubic intravaginal sling (IVS) when a bladder injury was noticed and sutured immediately. Postoperative complications occurred in ten (9.6%) operations: Three patients had fever which resolved after antibiotic treatment. Five patients had postoperative hematomas, three required reoperation for drainage, and two patients were treated conservatively. One patient required blood transfusion and one Venofer infusion. Among the postoperative hematomas, two occurred after complete mesh removal, one after laparoscopy, one after urethrolysis, and one after search for residual mesh. Other postoperative complications were: One patient had continuous bleeding and was reoperated for hemostasis. The patient with the bladder injury during section of retropubic IVS had a postoperative complication with vesico-vaginal fistula and was reoperated after 3 weeks with no further consequences.

Patients were followed routinely 6 weeks and 6 months after the operation. Nineteen patients (18% of 104 operations) did not show up for the 6-month consultation. Recurrence of POP or SUI was observed in 22 patients. All prolapse recurrences were of cystoceles. Overall, there were 42 operations for removal of vesico-vaginal meshes and eight cases (19%) of cystocele recurrence. Seven cystoceles recurred after complete mesh removal and one after partial removal. Seven patients underwent reoperation for prolapse: three with revaginal mesh and four went through laparoscopic sacrocolpopexy. SUI recurred in 14 patients (37.8% of all sub-urethral sling interventions): Eight cases recurred after complete removal of sub-urethral sling, four after section of the band, one after laparoscopic excision of TVT, and one after partial removal. Ten patients underwent reoperation for SUI: four with TOT and six had retropubic IVS with readjustment the following day.

Discussion

In pelvic reconstructive surgery, recurrence of genital prolapse, especially of cystocele, is one of the main concerns and can reach up to 40% [14, 15]. The high recurrence rate of POP after repair with autologous tissues, along with the introduction of mesh to treat incontinence by the TVT [16], resulted in a dramatic progress and development of transvaginal mesh surgery. It seems to us that since the commercial kits for vaginal mesh surgery are very popular today, there are many untrained surgeons placing vaginal meshes to treat prolapse and SUI, lacking the right anatomical knowledge of the pelvic floor. This situation enhances the risk of complications, sometimes very severe. Furthermore, when complications occur, the lack of knowledge and experience can cause further severe morbidity if it is not diagnosed and treated in a proper way. Complications of vaginal mesh are often overestimated, sometimes overemphasized and often poorly described and managed [17]. Our aim was to reveal the way we treat vaginal mesh complications in a trained tertiary referral center.

Over the course of 5 years, we had 104 operations for mesh removal due to various complications. During that period, we performed more than 1,200 vaginal mesh operations for SUI and POP. Our overall complication rate was less than 10%. Taking into consideration that patients were also referred to us with complications from other centers, mesh-related complication rate was probably even lower than 10%, as we have recently published [18].

Table 3 Characteristics of the major groups of surgical transvaginal mesh removal

Intervention	Patients (*n*)	Operations (*n*)	Mean age (year)	Mean op time (min)	Mean hos stay (days)	Indication (*n*)	Complications		Recurrence (*n*)
							Pre-op	Post-op	
Complete removal	57	61	62.8	21.08	3.1	Erosion (31) Infection (22) Mal position (3) Granuloma (5) Incomplete voiding (2) Sub-urethral collection (1)	None	2 Hematoma 2 Fever 1 Continuous bleeding	Cystocele (7) SUI (8)
Partial removal	14	14	60.9	14.5	2.5	Erosion (11) Granuloma (2) Dyspareunia (1)	None	None	Cystocele (1) SUI (1)
Laparoscopy	5	5	57.4	46.25	5.2	Pelvic pain (4) Rec. UTI (1)	1 Converted into laparotomy	1 Retzius' hematoma	SUI (1)
Section	14	15	61.8	9.2	1.3	Incomplete voiding (13) Pain (2)	1 Bladder injury	1 Vesico-vaginal fistula	SUI (4)

op operation, *hos* hospital, *rec* recurrent, *UTI* urinary tract infection, *SUI* stress urinary incontinence

Table 4 Recurrent cases of operative mesh removal: indications for the primary and the sequential operations

Primary operation (*n*)	Secondary operation (*n*)
Erosion (10)	Recurrent erosion (5)
	Infection (5)
Infection (4)	Recurrent infections (4)
Granuloma (1)	Infection (1)
Incomplete voiding (1)	Persistent incomplete voiding (1)
Recurrent UTI (1)	De novo pain (1)

UTI urinary tract infections

Women were addressed for various symptoms, mostly abnormal discharge, bleeding, pain, and voiding difficulties. Not every mesh-related complication required complete mesh excision, although most of the operations were of complete mesh removals. The decision whether to perform a partial or complete mesh removal in cases of erosion depends mainly on our concern for recurrence. We will always prefer to remove the mesh completely in case of repeat erosion, in any case of suspected underlying infection (when the mesh is surrounded by slime), or when during clinical examination the mesh is found to be self-dissected from the surrounding tissues, which, according to our knowledge and experience, is a sign of mesh rejection. Fourteen patients underwent partial removal of the mesh: 11 patients had small erosion, two had granuloma, and one dyspareunia. For ten out of 14 patients (71.4%), removal of the extruded part was sufficient with no further consequences, as described in other series [19]. However, four patients with simple erosion, which underwent partial removal, required reintervention: three because of infection and one had recurrent erosion, and they all went through complete mesh removal for the secondary procedures. Altogether, 17 out of 83 patients (20.5%) required multiple procedures for mesh removal, and five patients were involved in more than two operations. These five patients had infection which recurred few times until a complete ablation of the mesh was achieved.

The most frequent mesh-related complications described in the literature are erosion, infection, pain, and shrinkage of the mesh [7, 19, 20], and the distribution of the indications for mesh removal in our series were as expected. The most frequent complications were erosion and infection (42% and 28.8%, respectively). Incomplete voiding was the indication for 44% of sub-urethral sling operations and was the leading cause for section of the band. Pain was the cause for nine operations, although only in six cases was it the major cause. In four patients, pain appeared after placement of TVT, and it was the cause for 80% of laparoscopic TVT removals. Four patients with recurrent prolapse and recurrent urinary tract infection

(UTI) were diagnosed as a malposition of the mesh, and it was an indication for mesh removal. Malposition of the mesh can be diagnosed during vaginal examination when the mesh is felt shifted on one side, and it can be also diagnosed by ultrasound. Shrinkage of the mesh is a complication described widely [17, 19, 21] that can result in severe deformation of the vagina causing dyspareunia, defecatory, and urinary dysfunction. In our department, we never join the anterior and the posterior mesh during prolapse repair. We have the feeling that it may reduce the risk of shrinkages of the mesh. Another severe and serious complication described in other series is the formation of fistula between the vagina and the rectum or the bladder [10, 11]. We had 104 operations for mesh excision; none was because of this kind of fistula. It appears that such a complication is very rare.

Most of the current publications about vaginal mesh operations report only short and medium term follow-up results. Thus, most of mesh complications appear to occur within the first postoperative year. In our series, we have found mesh-related complications even 8 years after mesh placement. Moreover, in 58 mesh removals (55.8%), the delay from the primary operation was more than 2 years. The most surprising finding was the high percentage of infections which appeared more than 2 years after the primary operation. In most cases of infected mesh, the cultures were sterile, and only in seven cases was there a detection of a pathogen. The diagnosis of infection was made upon abnormal secretion, pus, and fistulization to the skin at the level of the needle scar. Similar reports in the literature have also failed to detect specific pathogen [22], and most infections are described within the first year. The causes for graft infection were studied since the beginning of graft use [23] along with the debate of its nature. The type of mesh which is used probably plays a major role in the appearance of some of the mesh-related complications [24, 25], and infections have nearly disappeared since the generalized use of knitted polypropylene monofilaments implants [17, 26]. It seems, according to the current knowledge and our findings, that the infections are of chronic nature, without a specific pathogen, and in most cases sterile. More biological researches are needed in order to try and detect responsible pathogens. On the other hand, the lack of pathogen in most cultures may imply that these patients have chronic inflammation and foreign body rejection which may play a role in the development of these complications and can explain the long delay after the primary operation.

Intra- and postoperative mesh removal complications were not very frequent. Minor postoperative complications occurred in nine patients and were most often hematomas or fever, treated conservatively in most cases. Four patients needed repeat intervention: three for drainage of the hematoma and one for hemostasis. Intraoperative complications were very rare and observed in two cases: The first was during laparoscopic removal of TVT which converted into laparotomy because of difficult hemostasis. In this case, laparoscopy was the second operation for removal of TVT after first attempt vaginally. This patient had an additional operation for the third time because of residual mesh. The other intraoperative complication occurred during section of retropubic IVS. During the procedure, a bladder injury was noticed and sutured immediately. This patient was found to have postoperative vesico-vaginal fistula, and she was reoperated after 3 weeks with no further sequences. Incomplete voiding after sub-urethral sling is a complication which can be observed between 1.5% and 22% of patients [27], and urethrolysis rate after TVT was described between 2.3% and 8% [28]. However, complications and outcomes after section of the band due to persistent voiding difficulties are not well described in the literature. During a course of 5 years, we had 15 sections of sub-urethral slings or the anterior arm of the cystocele mesh due to incomplete voiding. Since we do not have the exact numbers of the overall sub-urethral sling operations performed during this period, we cannot asses the correct rate of this complication, although it was not very frequent. Although section of the band is a rather simple procedure and in most cases can be carried out under local anesthesia, complications can occur as we have described, and in four patients, recurrence of SUI was observed.

Recurrence of POP or SUI after excision of the mesh is an interesting issue. Eight patients had recurrence of prolapse and all were cystoceles. It is 19% out of 42 operations for cystocele mesh (vesico-vaginal mesh) removal and 11.4% out of all the 70 operations for vaginal mesh removal (28 recto-vaginal and 42 vesico-vaginal). This observation is consistent with the known fact that most recurrences are in the anterior vaginal wall [14]. Nevertheless, for almost 80% of the patients, the prolapse did not recur although the mesh was removed. Seven cystoceles recurred after complete mesh removal, and one recurred after partial removal of the mesh. The indications for the removal of the mesh were variable: five cases of erosion, two cases of infection, and one case of persistent voiding difficulties and recurrent UTI. Four removals were preformed less than 1 year after the primary operation (range, 3 weeks–6 months) and four were between 1 and 3 years after the primary operation. Most cystoceles recurred within 6 months after the removal of the mesh, while pelvic organ prolapse quantification (POP-Q) before the removal of the mesh did not reveal any case of prolapse. The cystoceles which recurred were all symptomatic with Ba from 0 to +3 according to POP-Q. In two patients, the recurrence of the cystocele after the mesh removal was accompanied by de novo central and posterior defects, and they underwent

laparoscopic sacrocolpopexy. No correlation was found between the recurrence of prolapse and the course of the mesh removal procedure. Most procedures were benign except for one patient which had postoperative hematoma. Recurrence of SUI after removal or section of sub-urethral sling was even more pronounced. There were 14 cases (37.8%) of SUI recurrences after 37 sub-urethral sling operations. Four occurred after section of the band, nine after complete removal, and one after partial removal. Thus, recurrence of SUI is much more frequent after mesh removal than POP. In all recurrences, POP and SUI, no correlation was found between mesh removal within the first year and recurrence. It seems to us that the body reaction with the mesh after prolapse operations is sufficient enough to prevent recurrence in most cases even after total removal of the mesh. But we have no information about the long-term recurrence in these patients. On the contrary, the high rate of SUI recurrence even after partial or section of the sling might also be explained by the body reaction with the mesh. It might be that the narrow sub-urethral sling is not enough to provoke a foreign body reaction which can last after the removal of the mesh, and once the band is removed, the SUI is likely to recur.

This case series has some drawbacks. The impact of this study is limited by its retrospective and descriptive nature and therefore susceptible to recall and interpretation biases. Moreover, since the data were collected retrospectively, 18% of the patients had no follow-up after 6 weeks. Since our hospital is a referral center, all patients with complications and recurrences are referred to us. Thus, we assumed that these patients had no further complications. The impact of the procedures on quality of life and sexual function was not in the frame of the current study, so it might be lacking for the whole assessment of the functional results. Validated questionnaires will be sent soon to all the patients in this study for further assessment of the long-term outcomes. However, despite its limitations, this series is strengthened by its size, which is the largest in the current literature, and the fact that all operations were performed in one center using the same technique and surgeons.

Conclusion

In a trained center, mesh removal is a quick and safe procedure with very few intra- and postoperative complications. Patients should be aware of mesh-related complications and be advised to return to their surgeons in case of any problem. Mesh complications may frequently occur more than 2 years after the primary operation, exceeding the current period known from short follow-up publications. Recurrence after mesh removal is mostly associated with SUI and less with POP. We encourage surgeons to further expand their anatomical knowledge, obtain specialized training for each mesh placement technique, and be aware of its risks. It is the only way to reduce serious associated mesh complications and to increase the knowledge and the experience of how to treat them when they occur.

Conflicts of interest None.

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